Title: Weight Loss and Exercise for Communities With Arthritis in North Carolina
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Wake Forest®
School of Medicine

Department of Health and Exercise Science

Weight loss and **E**xercise for **C**ommunities with **A**rthritis in **N**orth Carolina (WE-CAN)

Informed Consent Form to Participate in Research

Stephen P. Messier, PhD, Principal Investigator

A. Summary

You are invited to participate in a research study. The purpose of this research is to examine the effects of an exercise and diet intervention on knee pain and physical function. You are invited to be in this study because you have knee pain. Your participation in this research will involve 4 testing visits and an 18-month intervention and last about 20 months.

Participation in this study will involve screening and baseline testing and either a diet and exercise intervention or a nutrition and health intervention. All research studies involve some risks. A risk to this study that you should be aware of is a risk of falling due to walking. There is the possibility that you may benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Some other choices may include conventional medicine. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Stephen Messier, PhD. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is: [redacted].

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

Introduction

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You may or may not receive any benefit from being part of the study. There may also be risks associated with being part of research studies. You are being asked to take part in this study because you have Knee Osteoarthritis. Your participation is voluntary. Please take your time to make your decision, and ask the study staff or the study doctor to explain any words or information that you do not understand. You may also discuss the study with your friends and family.

Why Is This Study Being Done?

Osteoarthritis (OA) is the most common form of arthritis. It is very common to get arthritis in your knee. While there are no cures for OA, treatment usually combines therapies, for example, exercise combined with a medication. The purpose of this research study is to examine the effects of an exercise and diet intervention on knee pain and physical function. Our research group has previously conducted a similar trial however with this trial we plan to conduct the first long-term effectiveness trial of intensive diet and exercise in older adults with knee OA under more usual conditions in both rural and urban communities across North Carolina.

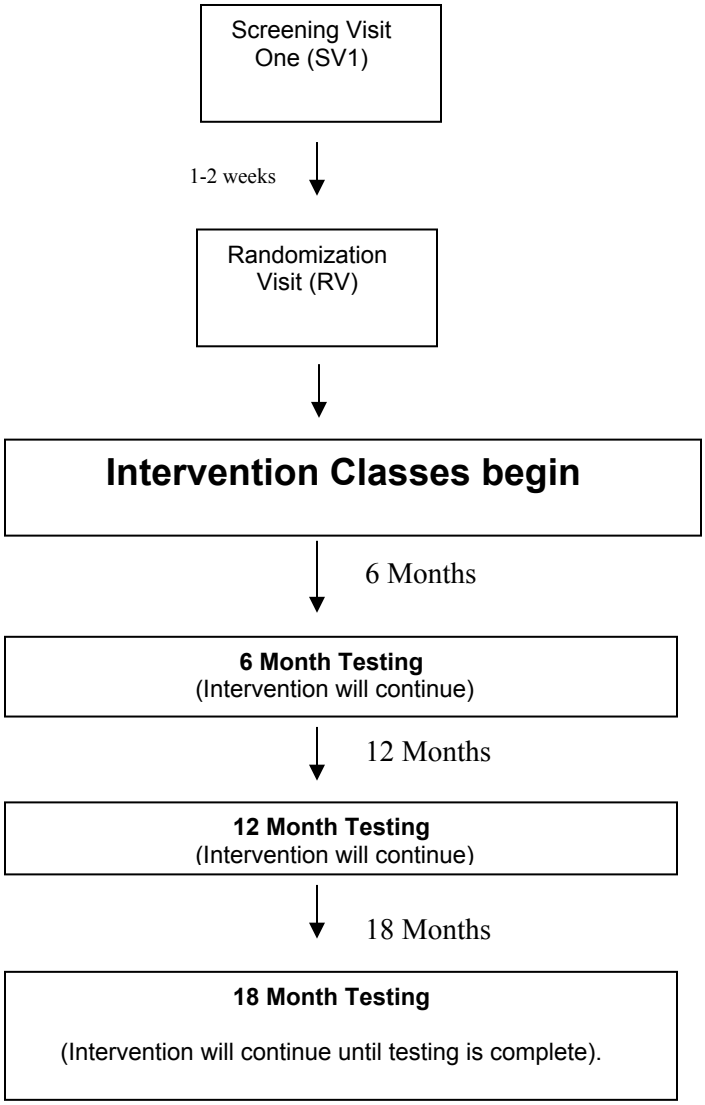
How Many People Will Take Part in the Study?

A total of up to 840 people at 3 research sites within North Carolina (Forsyth County, Johnston County, and Haywood County) will take part in this study, including approximately 420 people at this research site. In order to identify the 420 subjects needed, we may need to screen as many as 810 because some people will not qualify to be included in the study. Only those who complete and pass the screening visits as listed below will be randomized into the study.

What Is Involved in the Study?

If you qualify to participate, you will undergo screening and baseline testing. The following scheduled visits and procedures will be performed.

Time line (A detailed description of the visits can be found following this figure).



Screening Visit 1 (SV1):

- *Worrell Professional Center at Wake Forest University:* The study will be described in detail and you will be asked to sign this consent form and give the research staff member your medication use and medical history forms that were previously mailed to you. The staff member will review the forms with you to make sure everything is correct. Your height, weight, and hip and waist circumference measurements will be taken and you will undergo a knee exam. You will also have your blood pressure measured.
- You will perform a 6-minute walk test (where we measure the distance you walk in 6 minutes). A balance, walking speed, stair climb, and chair rise test will also be

performed. You will complete questionnaires, including general background, knee pain, physical disability, physical function, physical activity history, confidence, eating habits, mental state and health status.
- This visit will take approximately 3 - 4 hours to complete.

Randomization Visit (RV):

Worrell Professional Center at Wake Forest University: You will be randomized to one of the study group assignments described below: diet + exercise or nutrition and health. You will remain in this group for the entire study. Randomization means that you are put into a group by chance by a special computer program, similar to flipping a coin. This is done so that a fair evaluation of results can be made. You will have a one in two chance of being placed in any one group.

- Below is a description of the 2 different study groups (you will be randomized into one of these groups):

DIET & EXERCISE GROUP

- ***Diet Intervention***
  - If you are randomly assigned to the diet and exercise group, you will be asked to carefully monitor how much you eat and to follow a low-calorie diet designed for you, with the goal of losing weight. The diet will include up to 2 meal replacements per day for 6 months, similar to Slim Fast liquid supplements (the meal replacements will be provided by the study). For the second/third meals, you will follow a weekly menu plan and recipes composed of traditional foods. The nutritionist will help you to develop a food plan for the second and/or third meal that is modified to your individual preferences.
  - You will attend regular classes once a week for about an hour over 6 months to help you with your diet program. The classes will consist of alternating weekly individual and group sessions (2 individual sessions and 2 group sessions per month). The individual sessions will alternate between face-to-face meetings with the nutrition interventionist and a method preferred by you (phone, email, text, etc.)
  - During the following 6 months of the study, you will attend one group session and one individual session per month. Once again, the individual sessions will alternate between face-to-face meetings and a method preferred by you (phone, email, text, etc.). During this phase the meal replacements will be provided.
  - Class topics for the group sessions include: changing eating habits to lower caloric intake, information regarding what food changes to make, how to make them, and why they are important. Each group session will also include problem solving, review of a specific food topic, and tasting of several well-balanced, low-fat, foods. During the individual sessions, the nutrition interventionist will review individual progress, solve problems, answer questions, and help you to set your program goals. The minimal weight loss goal is 10% of your body weight (approximately 20 pounds for a 200 pound person). Some people will lose more weight than that, and others will lose less.

- During the last 6 months of the study, you will attend one monthly individual session. The nutrition interventionist will review individual progress, solve problems, answer questions, and assist you in trying to achieve your program goals.
- Your in-person, face-to-face nutrition classes will be held before or after your exercise classes to make participation easier for you.

- ***Exercise Intervention***
  - You will begin coming to exercise classes 3 days per week for an hour each day. The class will consist of 15 minutes of an aerobic activity (walking, stationary bikes, elliptical trainer, etc), followed by 20 minutes of strength training involving leg weights, bands, and/or machines, followed by another 15 minutes of aerobic activity, and 10 minutes of cool-down exercises. The goal of the exercise program is to improve your fitness. Your exercise instructor will monitor your progress and will help you reach your fitness goals. These regular exercise classes will go on for 18 months.
  - The diet and exercise classes will be held at various locations within Winston-Salem. You will be given the option on which location you would like to attend. Classes will be held at the Clinical Research Center at Wake Forest University Campus and at Innovation Quarter YMCA.
  - A 1 mile & 5K walk event will be scheduled during the 18 month intervention to encourage physical activity. You will not be required to participate in this event. In order to participate you will be asked to sign a waiver. The walk will take place at Wake Forest University.

NUTRITION AND HEALTH GROUP

- You will attend 5 group session classes over the 18-month period. The face-to-face group meetings will occur at months 1, 3, 6, 9, and 15. During the other months (months 2, 4-5, 7-8, 10-14, 16-18) you will receive a combination of phone calls, emails, text messages, video messages (you will receive materials based on your preferred method).
- You will be provided with information on healthy eating and health behaviors. The information will cover various health topics on nutrition, health & wellness, and chronic diseases. Experts will give wide-ranging lectures.
- The face-to-face group meetings will be held at the Winston-Salem Senior Services Center and at Wake Downtown in Winston-Salem, NC.
- You will be compensated $100 if you complete all testing visits. You will receive $25 after completing the 6-month testing visit and $75 after completing the 18-month testing visit.

<u>6 Month Follow-up Visit (FU6):</u> You will return for a follow up visit after 6 months.
(Wake Forest University): You will have your blood pressure, weight, hip, and waist measured. You will perform the 6-minute walk and the stair climb, balance, walking speed, and chair rise tests that were performed at baseline. Your medical history and medications (previously mailed) will be reviewed. You will be given the questionnaires

that were given at baseline to complete at the end of this visit. This visit should last approximately 2.5 – 3.5 hours.

12 Month Follow-up Visit (FU12): You will return for a follow up visit after 12 months. *(Wake Forest University)*: You will have your blood pressure, weight, hip, and waist measured. You will perform the 6-minute walk and the stair climb, balance, walking speed, and chair rise tests that were performed at baseline. Your medical history and medications (previously mailed) will be reviewed. You will be given the questionnaires that were given at baseline to complete at the end of this visit. This visit should last approximately 2.5 – 3.5 hours.

18 Month Follow-up Visit (FU18): You will return for a follow up visit after 18 months. *(Wake Forest University)*: You will have your blood pressure, weight, hip, and waist measured. You will perform the 6-minute walk and the stair climb, balance, walking speed, and

chair rise tests that were performed at baseline. Your mental status will be measured. Your medical history and medications (previously mailed) will be reviewed. You will be given the questionnaires that were given at baseline to complete at the end of this visit. This visit should last approximately 2.5 – 3.5 hours.

How Long Will I Be in the Study?

You will be in the study for about 20 months including testing visits.

You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. There are no serious health or safety consequences that will occur if you choose to stop participating.

What Are the Risks of the Study?

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff.

- There may be muscle or joint soreness following the physical performance test (six minute walk/stair climb) or exercise. These symptoms usually go away quickly and are usually not serious.
- It is possible to have a more serious injury, such as a torn ligament or sprain from these tests, but this is extremely rare. Your tests will be monitored very closely to provide a high degree of safety for you.
- There is a small chance that exercise could lead to symptoms of heart disease or minor injury. Some examples of these symptoms include shortness of breath, irregular heart beat, skipped beats, a "flip-flop" feeling in your chest, weakness or dizziness, upset stomach, or a painful, heaviness, or discomfort feeling in your chest. There is a slight risk of falling during the walking portion of testing and training. Rarely, 1-2%, of older people with arthritis who

exercise will suffer more serious injury such as a broken bone from a fall. Exercise participants will have continuous safety monitoring during all training and testing, which will help make sure participants will exercise safely. Pain associated with exercise usually goes away after a few days.

- There is a chance that you may experience some discomforts as a result of dieting such as hunger or a feeling of less energy. The meal plan will be developed by the nutrition staff to meet your individual needs and will consist of a balanced diet to minimize these discomforts. In addition the meal plan will include snacks in between your meals to minimize the feeling of hunger.
- There is a small risk that participants may lose too much weight. Your weight will be monitored regularly to reduce the chances of this occurring. In addition, some persons who diet may have dietary deficiencies; your food diaries will be reviewed weekly to make sure that you are getting all the nutrients you need.
- There also may be other side effects that we cannot predict. You should tell the research staff about any medicine, vitamins, or supplements you take and any medical problems you have. This may help avoid side effects and other risks.
- Taking part in this research study may involve providing information that you consider confidential or private. Dr. Stephen Messier and his research staff will protect your records so that all your identifying information (name, address, phone number, information in your health record) is kept private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe. In addition an internal safety committee will be reviewing the data from this research throughout the study.

  A Data Safety and Monitoring Committee, an independent group of experts, will be reviewing the data from this research throughout the study.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires

disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by NIH which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect, or harm to self or others. The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document (collection of health data).

Are There Benefits to Taking Part in the Study?

If you agree to take part in this study, there may or may not be any direct benefit to you. We hope the information learned from this study will benefit other people in the future. You may benefit by having reduced pain, improved physical function, and/or weight loss.

Based on experience with diet and exercise in other studies with persons with knee osteoarthritis, researchers believe that diet and exercise are important in preventing disease and disability. Previous studies have shown that weight loss helps to decrease pain and improve function in persons with knee osteoarthritis. Because individuals respond differently to therapy, no one can know in advance if it will be helpful in your particular case. Information received in the nutrition and health classes will provide valuable health information. In addition, each participant will contribute to our knowledge about osteoarthritis and may aid in our attempt to reduce or eliminate some disabilities associated with the disease.

What Other Choices Are There?

You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have. The tests and medications provided are available in the community; these usually involve a charge to participants. Instead of being in this study, you have the option of being treated with conventional medical therapy.

What about My Health Information?

In this research study, any new information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** health history, your family health history, how you respond to study activities or procedures, and information from study visits, phone calls, surveys, and physical examinations.

If this research study involves the treatment or diagnosis of a medical condition, then Protected Health Information collected from you during the study may be placed in your medical record and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office and on a password

protected website and computer. Only the following people or organizations will be granted access to your Protected Health Information:

1) The study investigator and his/her staff, or others at Wake Forest University Health Sciences who oversee research

2) Other people or laboratories providing services for this research project on behalf of Wake Forest University Health Sciences and Wake Forest University Baptist Medical Center

3) Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for an indeterminate period of time. This authorization does not expire. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Stephen Messier that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people

who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

What Are the Costs?

There are no costs to you for taking part in this study. All the study costs, including any study tests, classes, and meal replacements related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

Will I receive Transportation or Free Parking?

The study will not provide transportation or reimbursement for parking.

Will You Be Paid for Participating?

Participants in the Nutrition and Health Group will be paid *$100* after completing the scheduled study visits ($25 for the 6-month testing visit and $75 for the 18-month testing visit). If you withdraw for any reason from the study before completion you will be paid *$25* if you completed the 6-month study visit.

To receive payment, you must provide your social security number, name and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not let them know what the payment is for, only that you have been paid. If you do not wish to provide this information you can still take part in this study but you will not be paid.

Who is Sponsoring this Study?

This study is being sponsored by *the National Institutes of Health, General Nutrition Center, and Wake Forest University*. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

What Happens if You Experience an Injury or Illness as a Result of Participating in this Study?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these

medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at [redacted]

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Stephen Messier [redacted] or after hours [redacted] or the project manager at [redacted]

What Are My Rights as a Research Study Participant?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because but not limited to, not following the study schedule; a change in your medical condition; or new information that necessitates study closure.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

Whom Do I Call if I Have Questions or Problems?

For questions about the study or in the event of a research-related injury, contact the site investigator, Stephen Messier at [redacted] or after hours [redacted] or the project manager at [redacted]

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted]

You will be given a signed copy of this consent form.

Signatures

a. I agree that Stephen P. Messier or someone whom he chooses may contact me in the future to ask me about taking part in more research. (*You may still participate if you do not wish to be contacted in the future*.) Yes __ No __

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm